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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,597	02/19/2004	Bruce S. McLean	7678.858	1616

7590 04/05/2005

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EXAMINER

O'CONNOR, CARY E

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/783,597	Applicant(s) MCLEAN ET AL	
	Examiner Cary E. O'Connor	Art Unit 3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-49 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6-10-04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5, 6, 20 and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Fischer et al (2004/0214140). Fischer shows a tray shaped dental treatment device 10 comprising a moisture resistant barrier layer having a front side wall and a bottom wall. The bottom wall includes a plurality of cuts 27 positioned so as to help the bottom wall conform to changes in the diameter of a person's teeth. A dental treatment composition is contained within the device (paragraph 0037, lines 9-11). As to claim 2, note the exoskeleton disclosed in paragraph 0058. As to claim 3, note the handle 20. As to claims 5 and 6, note paragraph 0038, lines 3-4. As to claims 20 and 38, note paragraph 0044.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 37 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischer (6,183,251). Fischer shows a tray shaped dental treatment device 22 comprising a moisture resistant barrier layer having a front side wall and a bottom wall. The bottom wall includes at least one V-shaped indentation configured to be inserted into the depression typically found along the top surfaces of a person's molars (see figure 4). The front wall and bottom wall includes a radii of curvature that account for typical flaring of a patient's incisors (see figure 3). A dental treatment composition is contained within the device

Claims 1, 5, 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Quisling (3,625,215). Quisling shows a tray shaped dental treatment device 10 comprising a moisture resistant barrier layer having a front side wall 11 and a bottom wall 12. The bottom wall includes a plurality of cuts 12b positioned so as to help the bottom wall conform to changes in the diameter of a person's teeth. A dental treatment composition 15 is contained within the device.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quisling (3,625,215) in view of Jacobs et al (2004/0002035). The tray of Quisling employs slits rather than notches. Jacobs shows a dental tray device wherein notches

27, 29 are used to enable the back wall to conform to the curvature of the patient's teeth. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use notches rather than slits in the tray of Quisling, in view of Jacobs, in order to reduce the amount of material on the back side of the teeth thereby making the tray more comfortable to use.

Claims 7-17, 21, 22, 30-36, 42-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quisling (3,625,215) in view of Chang (2003/0194382). Quisling does not disclose the specifics of the composition and does not include a tissue adhesion agent. Chang shows an article of manufacture for bleaching teeth comprising an adhesive layer that provides substantial adhesive strength when hydrated by water. This type of adhesive does not stick to the hands or face during application, thereby making the article easier to handle. The article also includes a bleaching agent. It would have been obvious to one of ordinary skill in the art to provide the tray of Quisling with a bleaching agent comprising a gel and a tissue adhesion agent, in view of Chang, so that the tray may be used to whiten teeth and the adhesive would hold the tray on the teeth better. As to claims 11, 12, note paragraph 0041 of Chang. As to claims 14 and 15, note paragraph 0071 of Chang which discloses that the tooth adhesion agent having a concentration of about 20% by weight of the adhesive composition. As to claim 15, Chang does not disclose that the adhesion agent has a concentration in a range of about 40% to about 75% by weight of the adhesive composition. At the time the invention was made, it would have been obvious matter of design choice to a person of ordinary skill in the art to form the adhesive composition having the adhesive

agent in the range of 40% to about 75% by weight because applicant has not disclosed that this range of concentration provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with the concentration in the range claimed by applicant. As to claim 17, note that Chang discloses a pouch for storage in paragraph 0062. As to claim 30, at the time the invention was made, it would have been obvious matter of design choice to a person of ordinary skill in the art to form the barrier layer with a thickness in the range of 0.025 mm to about 1.5 mm because applicant has not disclosed that this range of thickness provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with the thickness in the range claimed by applicant.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer et al (2004/0214140) in view of Fischer (6,183,251). The tray of Fisher '140 does not include a v-shaped or u-shaped indentation in the bottom wall or that the front wall and bottom wall includes a radii of curvature that account for typical flaring of a patient's incisors. Fischer '251 shows a tray shaped dental treatment device 22 comprising a moisture resistant barrier layer having a front side wall and a bottom wall. The bottom wall includes at least one V-shaped indentation configured to be inserted into the depression typically found along the top surfaces of a person's molars (see figure 4). The front wall and bottom wall includes a radii of curvature that account for typical flaring of a patient's incisors (see figure 3). It would have been obvious to one of

ordinary skill in the art at the time the invention was made to form a v-shaped or u-shaped indentation in the bottom wall of Fischer '140 and form the front wall and bottom wall to include a radii of curvature that account for typical flaring of a patient's incisor, in view of Fischer '251, so that the tray will fit more firmly over the teeth and resist accidental displacement.

Claims 24-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quisling (3,625,215) in view of Chang (2003/0194382) as applied to claim 21 above, and further in view of Sagel et al (2002/0018754). Quisling does not disclose that the polyolefin comprises at least one of polyethylene, high density polyethylene, low density polyethylene, ultra-low density polyethylene, polypropylene, or polytetrafluoroethylene. Sagel shows an article of manufacture comprising a barrier layer made of polyethylene or polytetrafluoroethylene (paragraph 0038). These materials are compatible with the bleaching agents. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use polyethylene or polytetrafluoroethylene as the barrier layer in Quisling, in view of Sagel, because these materials are compatible with the bleaching agents. As to claims 24-26, at the time the invention was made, it would have been obvious matter of design choice to a person of ordinary skill in the art to form the barrier layer comprising up to 50% polypropylene by weight, because applicant has not disclosed that this range of thickness provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with the thickness in the range claimed by applicant.

Claims 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quisling (3,625,215) in view of Andreiko (5,752,826). Quisling does not disclose that a plurality of devices are stacked and interested together. Andreiko shows a single use dental impression tray and discloses that a plurality of the trays may be stacked together for easy storage (column 8, lines 5-6). It would have been obvious to one of ordinary skill in the art at the time the invention was made to store the devices of Quisling in a stacked condition, in view of Andreiko, for ease of storage.

Claim Objections

Claim 40 objected to because of the following informalities: In line 2, "interested" appears to be a typographical error. Appropriate correction is required.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: 203a (Fig. 2) and 303a (Fig. 3). A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cary E. O'Connor whose telephone number is 571-272-4715. The examiner can normally be reached on M-Th 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on 571-272-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Cary E. O'Connor
Primary Examiner
Art Unit 3732

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